UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,317	12/17/2003	Timothy A. Becker	65306-0092	8901

10291 7590 05/23/2007

RADER, FISHMAN & GRAUER PLLC
39533 WOODWARD AVENUE
SUITE 140
BLOOMFIELD HILLS, MI 48304-0610

EXAMINER	
ROGERS, JAMES WILLIAM	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
05/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/738,317	BECKER ET AL.	
	Examiner	Art Unit	
	James W. Rogers, Ph.D.	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 March 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-17,21-33 and 35-44* is/are pending in the application.

4a) Of the above claim(s) *38-44* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-17,21-33 and 35-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendments to the claim filed 03/20/2007 have been entered. Any rejection/objection from the previous office action dated 09/20/2006 not addressed in the action below has been withdrawn. Applicants have cancelled claims 2-4,18-20 and 34, the examiner has withdrawn claims 38-44, thus claims 1,5-17,21-33 and 35-37 are currently pending.

Election/Restrictions

Newly submitted claims 38-44 are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

I. Claims 1,5-17,21-33 and 35-37 drawn to a method of forming an endovascular occlusion comprising the step of controlling injection of purified alginate liquid and injection of a calcium chloride solution to a targeted area within a vascular system, classified in class 424, subclass 423.

II. Claims 38-44, drawn to a method for forming an endovascular occlusion comprising providing a catheter comprised of a microcatheter having a first lumen with a second catheter disposed inside the first lumen, the second catheter having a second lumen that is concentric with the first lumen, the distal end of the second lumen being adjustable with respect to the distal end of the first lumen and controlling injection of a purified alginate liquid and injection of a calcium chloride solution to the targeted are through the catheter, classified in class 604, subclass 508.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the endovascular occlusion can be formed without the use of the exact catheter as in invention II, for instance forming an endovascular occlusion by injecting either the alginate or calcium chloride solution through one catheter and then injecting the other solution through a second separate catheter so that the solutions meet at the target site and form an endovascular occlusion. The subcombination has separate utility for example an intravenous drug delivery device in which one drug can be supplied by the first lumen/catheter and then a second drug can be supplied through the second lumen/catheter.

The examiner has required restriction between combination and subcombination inventions. Where applicant elects a subcombination, and claims thereto are subsequently found allowable, any claim(s) depending from or otherwise requiring all the limitations of the allowable subcombination will be examined for patentability in accordance with 37 CFR 1.104. See MPEP § 821.04(a). Applicant is advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 38-44 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 5,8,9 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This new rejection was necessitated by amendment, because previously the injection of the purified alginate liquid and injection of the calcium chloride solution at variable injection rates was an optional limitation. By amendment the above limitation is no longer optional thus this new rejection was necessitated. Specifically claim 5,8,9 and 22 all recite that the flow rate for either the alginate and calcium solutions is continuous, this contradicts the limitation in claim 1 from which all the claims are dependent upon which states that the injection of the purified alginate liquid and injection of the calcium chloride solution occur at variable injection rates. Thus claims 5,8,9 and 22 are indefinite with respect to what flow rate is being claimed for the alginate or calcium solutions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 25-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kipke et al. (US 2001/0031978 A1) in view of Reeves (US 5,222,970) in view of Ji et al. (US 5,894,022).

Applicants arguments/remarks filed 03/20/2007 have been fully considered but are not persuasive.

Applicants assert that Kipke does not disclose injection of the purified alginate liquid and injection of the calcium chloride solution at variable injection rates within an injection state or across injection stages.

Since claims 25-26 do not recite this limitation this argument is moot.

Applicants assert that neither Reeves or Ji cure the deficiencies of Kipke and neither discloses any method or system for delivery and formation of a muti-component polymer and Ji does not form a polymer formed in vivo from a plurality of components. Applicants then assert that the examiners obviousness type rejection is an impermissible hindsight rejection.

The relevance of these assertions is unclear. Reeves is used only to show that using a catheter to inflate a balloon with a polymer for vascular occlusion was already known at the time of the invention and Ji is used only to show that using a polymeric occlusion agent in conjunction with another endovascular embolic material such as a coil was already known at the time of the invention. Since both these references are secondary references they do not have to meet all of applicants claimed invention on their own merit, the primary reference Kipke meets the limitation on controlled injections of calcium chloride and alginate solutions. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account

only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Claims 1,5-17,21-22 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cochrum (US 5,614,204, cited in office action dated 08/10/2005) in view of Kipke (US 2001/0031978 A1, cited in previous office action). This new rejection was necessitated by amendment, because previously the injection of the purified alginate liquid and injection of the calcium chloride solution at variable injection rates was an optional limitation. By amendment the above limitation is no longer optional thus this new rejection was necessitated.

Cochrum discloses vascular occlusion agents and a method for hemostatic occlusion, alginates can be selected as the angiographic occlusion agent. See abstract and col 3 lin 48-59. In one form of administration the biopolymer solution is injected in liquid form to the site where occlusion is needed and a calcium solution is independently added before, during or after the injection of the biopolymer in order to achieve complete occlusion of the vessel. See col 7 lin 58-65. The injection is by a catheter connected to a syringe with a plunger, the hand controls delivery of the solution. Since the human hand can control the flow rate at the will of the administrator and it is obvious that no matter how steady someone's hand is while injecting the solutions the flow rate of the solution when delivered by catheter will vary during the injection stage due to human muscle contraction variances. See Fig 1. Therefore applicants limitation that the

injection of the alginate/ calcium chloride solution are at variable rates within an injection stage or across injection stages is met by the disclosure of Cochrum. Regarding claims 15-16 Cochrum discloses that the alginate solution may also contain therapeutic agents. See col 13 lin 38-44.

Cochrum while disclosing forming vascular occlusions by injecting alginate and calcium solutions to the site intended for occlusion it is silent on the use of purified alginate solutions.

Kipke discloses a method for forming an endovascular occlusion comprised of controlling the injection rate and pressure of a purified alginate and calcium chloride solution. See abstract, [0003], [0013], [0015], [0035],[0071] and claims. Regarding claims 35 and 37 Kipke discloses that the concentration of the solution can be about 25 cp, the examiner considers about 25 cp to include viscosities slightly under 25cp therefore the limitation is met. See [0013]. Kipke also teaches several injection techniques including staged injections. Regarding claims 33-34 and 36, Kipke while disclosing the use of alginates with different guluronic acid and mannuronic acid content is silent on the exact MW of the alginates, although the examiner concludes that the Kipke application obviously incorporates the same alginates with the same MW because both applications bought the alginates from the same source (Pronova) and apparently used the same commercially available alginates.

It would have been prime facie obvious at the time of the invention to a person of ordinary skill in the art to modify the alginates disclosed in Cochrum and add the purified alginates disclosed within Kipke. It is generally considered to be prime facie obvious to

combine compounds each of which is taught by the prior art to be useful for the same purpose in order to form a composition that is to be used for an identical purpose. The motivation for combining them flows from their having been used individually in the prior art, and from them being recognized in the prior art as useful for the same purpose. As shown by the recited teachings, instant claims are no more than the combination of conventional components of compositions intended for vascular occlusion. There is also clear motivation to modify/replace the alginates of Cochrum with the alginates of Kipke because the purified alginates of Kipke show clear advantages to other alginates in regards to biocompatibility, strength and viscosity as shown in table 1 of Kipke. An artists of ordinary skill in the art would have a reasonable expectation of success in modifying/replacing the alginates of Cochrum with the purified alginates of Kipke because both publications use similar ingredients (alginates and calcium) in their compositions to provide the same disclosed intended use vascular occlusion, therefore the ingredients would be interchangeable. It therefore follows that the instant claims define prime facie obvious subject matter.

Claims 1,5-17,21-24, 27-33 and 35-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cochrum (US 5,614,204, cited in office action dated 08/10/2005) in view of Kipke et al. (US 2001/0031978 A1) in view of Ji et al. (US 5,894,022). This new rejection was necessitated by amendment, because previously the injection of the purified alginate liquid and injection of the calcium chloride solution at variable injection rates was an optional limitation. By amendment the above limitation is no longer optional thus this new rejection was necessitated.

Cochrum and Kipke are disclosed above. Neither Cochrum or Kipke disclose the use of a coil in conjunction with the purified alginate and calcium chloride.

Ji is used only to show that using a polymeric occlusion agent in conjunction with another endovascular embolic material such as a coil was already known at the time of the invention. See col 6 lin 23-38.

It would have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to combine the art described in the documents above because the combination of Cochrum and Kipke as above disclose the same polymeric alginate composition for vascular occlusion as applicants while Ji showed the use of a polymeric occlusion agent in conjunction with another endovascular embolic material such as a coil were already known at the time of the invention. The motivation to combine the above documents would be a method for vascular occlusion by controlling the injection of a purified alginate and calcium chloride solution that could also be used in conjunction with a coil. The benefit of the above method would be an administration that enables control of the occlusion agent to meet and polymerize at the target site. Thus, the claimed invention, taken as a whole was *prima facie* obvious over the combined teachings of the prior art.

Conclusion

No claims are allowed at this time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, THIS ACTION IS MADE FINAL. See MPEP §706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 8:30-5:00.
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 271-0616. The fax phone number for the organization where this application or proceeding is assigned is 572-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER